II

104TH CONGRESS
1ST SESSION

S. 1191

To provide for the availability of certain generic human and animal drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 11 (legislative day, JULY 10), 1995

Mr. PRYOR introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To provide for the availability of certain generic human and animal drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as ''The Consumer Access to Prescription Drugs Act of 1995''.

SEC. 2. APPROVAL AND MARKETING OF GENERIC DRUGS.

(a) APPROVAL OF APPLICATIONS.—For purposes of acceptance and consideration by the Secretary of an application under subsections (b), (c), and (j) of section 505, and subsections (b), (c), and (n) of section 512, of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b), (c), and (j), and 360b (b), (c), and (n)), the expiration date of a patent that is the subject of a certification under section 505(b)(2)(A) (ii), (iii), or (iv), section 505(j)(2)(A)(vii) (II), (III), or (IV), or section 512(n)(1)(H) (ii), (iii), or (iv), respectively, made in an application submitted prior to June 8, 1995, or in an application submitted on or after that date in which the applicant certifies that substantial investment was made prior to June 8, 1995, shall be deemed to be the date on which such patent would have expired under the law in effect on the day preceding December 8, 1994.

(b) RIGHT TO MARKET.—The remedies of section 271(e)(4) of title 35, United States Code, shall not apply to acts which—

(1) were commenced or for which a substantial investment was made prior to June 8, 1995; and

(2) became infringing by reason of section 154(c)(1) of such title, as amended by section 532 of the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4983).

(c) EQUITABLE REMUNERATION.—For acts described in subsection (b), equitable remuneration of the type described in section 154(c)(3) of title 35, United States Code, as amended by section 532 of the Uruguay

Round Agreements Act (Public Law 103–465; 108 Stat. 4983) may be awarded to a patentee only if there has been—

(1) the commercial manufacture, use, offer to sell, or sale, within the United States of an approved drug that is the subject of an application described in subsection (a); or

(2) the importation into the United States of an approved drug that is the subject of an application described in subsection (a).

SEC. 3. DEFINITIONS.

(a) ACTS WHICH WERE COMMENCED.—The submission of an application for approval of a drug under section 505(b)(2), 505(j), 507, or 512(n), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b)(2) and (j), 357, and 360b(n)) prior to June 8, 1995, or the subsequent making, using, offering to sell, selling, or importing of the drug which is the subject of the application, shall constitute acts which were commenced prior to June 8, 1995, as that term is used in this Act and in section 154(c)(2) of title 35, United States Code, as amended by section 532 of the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4983). A person who submits such application, and a person who supplied any active ingredient used by such person in such drug, shall be

deemed to have performed acts which were commenced prior to June 8, 1995.

(b) SUBSTANTIAL INVESTMENT.—The development of a product formulation and the manufacture of an experimental batch of a drug that becomes the subject of an application, or the initiation of stability or bioequivalency studies, by an applicant referred to in section 505(b)(2), 505(j), or 512(n), or by a manufacturer of a drug referred to in section 507, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b)(2) and (j), 360b(n), and 357) shall constitute substantial investment, as that term is used in this Act and in section 154(c)(2)(A) of title 35, United States Code, as amended by section 532 of the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4983). A person who supplied any active ingredient used by such applicant in such drug or by such manufacturer in such drug shall be deemed to have made substantial investment by having supplied the active ingredient to such applicant or such manufacturer.

SEC. 4. APPLICABILITY.

(a) APPLICABILITY TO APPROVAL OF APPLICATIONS.—The provisions of this Act shall govern—

(1) the approval or the effective date of approval of applications under section 505(b)(2), 505(j), 507, or 512(n), of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 355 (b)(2) and (j), 357, and 360b(n)) submitted on or after the date of enactment of this Act; and

(2) the approval or effective date of approval of all pending applications that have not received final approval as of the date of enactment of this Act.

(b) APPLICABILITY IN JUDICIAL PROCEEDINGS.—The provisions of this Act shall apply in any action that—

(1) relates to the approval or marketing of a drug or the infringement of a patent; and

(2)(A) is brought in a Federal or State court on or after the date of enactment of this Act; or

(B) is brought in a Federal or State court prior to the date of enactment of this Act and pending on such date.

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